

MINIMUM TESTING ALGORITHM

SEROLOGICAL DIAGNOSIS OF SYPHILIS

VSOP 44

Issued by Standards Unit, Evaluations and Standards Laboratory
Centre for Infections



UK Clinical Virology Network



Association of Medical Microbiologists



SEROLOGICAL DIAGNOSIS OF SYPHILIS

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STATUS OF NATIONAL STANDARD METHODS

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AMENDMENT PROCEDURE

Controlled document reference	VSOP 44
Controlled document title	Serological Diagnosis of Syphilis

Each National Standard Method has an individual record of amendments. The current amendments are listed on this page. The amendment history is available from standards@hpa.org.uk.

On issue of revised or new pages each controlled document should be updated by the copyholder in the laboratory.

Amendment Number/ Date	Issue no. Discarded	Insert Issue no.	Page	Section(s) involved	Amendment

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Syphilis has re-emerged as an increasing cause of outbreaks across England and Wales in recent years, following a period of rapid decline in numbers resulting in a period when very few cases were seen in the early 1990's. The current approach to the serological diagnosis of syphilis was established during this period of low numbers of positive cases. Many laboratories only dealt with a few positive cases and lacked experience in interpretation of serological results and therefore these positive sera were referred to regional and/or reference laboratories for further testing and confirmation.

In the current situation where syphilis does not appear to be in control there is some concern that referral of sera from patients with a positive screening test without further testing may incur a delay in providing the patient with a timely result. This can result from delays due to batching of sera before referral for confirmation, time spent at regional/reference centres and inherent delays in the generation and documentation of reports.

The minimum testing algorithm attempts to readdress this problem and suggests a minimum of tests that should be performed at the primary diagnostic laboratories (marked in red) before extended testing or confirmation which can be performed at a primary diagnostic laboratories with appropriate expertise or a regional/reference centre (marked in green). Discrepant samples or those with unusual profiles should always be referred to a regional/reference centre (marked in orange).

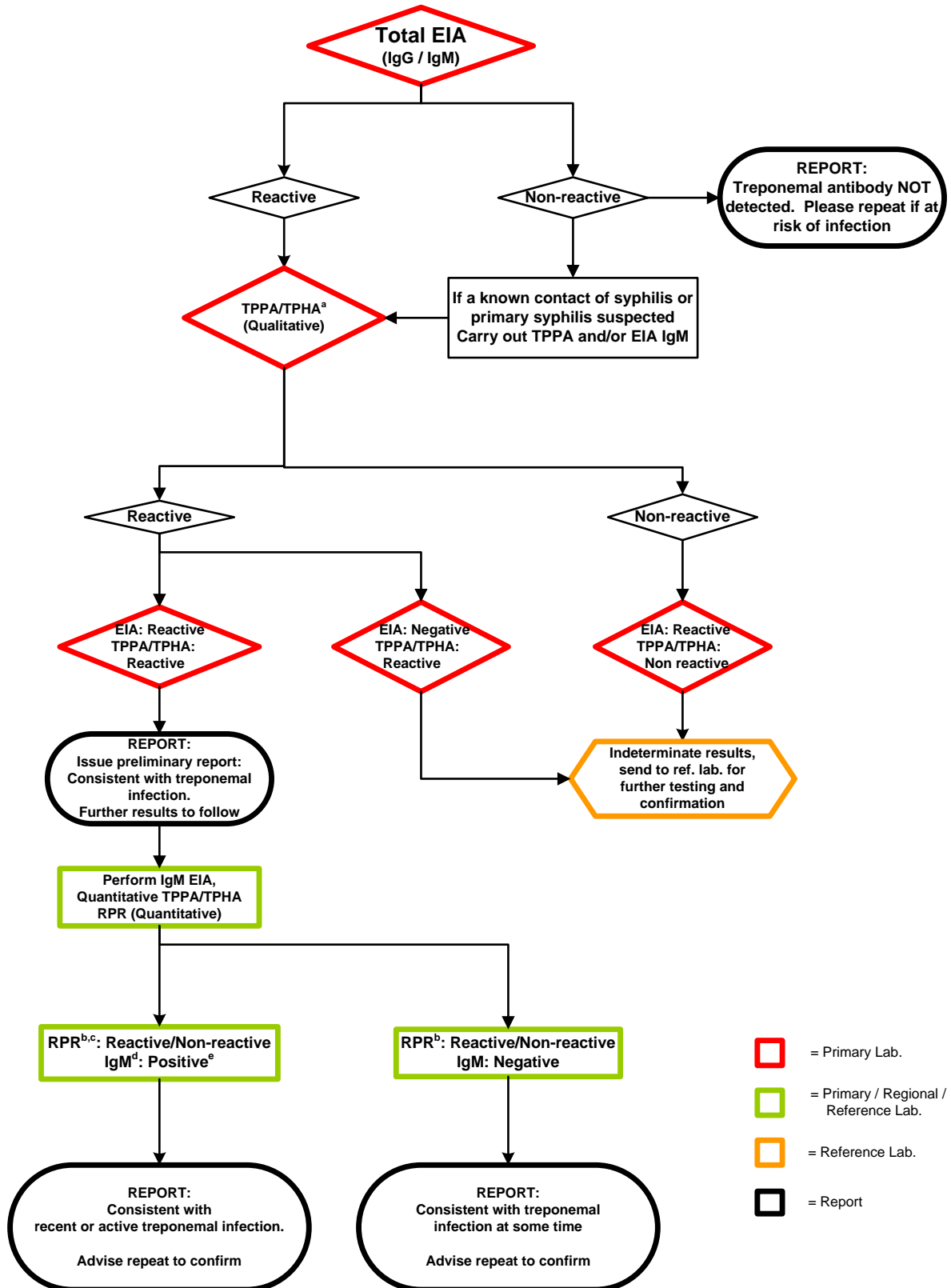
In this algorithm the EIA detecting both IgG/IgM has been chosen as the screening test as it is highly sensitive but slightly less specific than the TPPA/TPHA.

Note:

- If a patient is a known contact of syphilis or if primary syphilis is suspected then both EIA IgM and TPPA should be performed
- A second sample should be requested on all new patients to avoid the possibility of labelling, sampling or handling error giving rise to a false result
- The terms RPR and VDRL are used interchangeably. VDRL antigen is not easily obtained and hence most laboratories are using the RPR test

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Footnotes:

- a Carry out a clot check. A clot check is done to make sure that there has not been an aliquotting error. It is a repeat test done not from the separated aliquot of serum which has already been test and which has given the initially reactive result, but rather from the original tube of clotted blood which is likely to contain clot and some residual serum and which will have the original patient identifier label from the sender.
- b RPR titre is used in laboratories to help assess whether infection is likely to be recent or adequately treated; a persisting RPR titre of >16 is seldom seen in an adequately treated infection.
- c Failure of a fourfold fall in RPR titre by six months, and an eightfold fall by one year post-treatment raises concerns about treatment failure or reinfection. If the RPR or IgM titres rise significantly raise a concern about reinfection.
- d Treponemal IgM results must be interpreted with care. Positivity reflects active infection but can persist for 12-18 months after treatment of infection².
- e Low IgM levels can indicate: persisting antibody from a previous infection: new infection: nonspecific infection. Low IgM positive will vary depending on the kit used but falls near to the cut-off. A repeat should be requested to detect a rise or fall in antibody level.

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ACKNOWLEDGEMENTS AND CONTACTS

This National Standard Method was initiated and developed by Professor Catherine Ison of the Sexually Transmitted Bacterial Reference Laboratory and the National Standard Methods Working for Clinical Virology (http://www.hpa-standardmethods.org.uk/wg_virology.asp). The contributions of many individuals in clinical virology laboratories and specialist organisations who have provided information and comment during the development of this document, and final editing by the Medical Editor are acknowledged.

The National Standard Methods are issued by Standards Unit, Evaluations and Standards Laboratory, Centre for Infections, Health Protection Agency, London.

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